



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,791	10/22/2003	Alan R. Hirsch	INS-31875(1)	5622

22202 7590 12/29/2010
WHYTE HIRSCHBOECK DUDEK S C
INTELLECTUAL PROPERTY DEPARTMENT
555 EAST WELLS STREET, SUITE 1900
MILWAUKEE, WI 53202

EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
----------	--------------

1655

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

12/29/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptomailbox@whdlaw.com
jpolmatier@whdlaw.com

Office Action Summary	Application No. 10/690,791	Applicant(s) HIRSCH, ALAN R.	
	Examiner MICHELE FLOOD	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-9, 26, 27 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 26 and 42-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on October 4, 2010 with the cancellation of Claims 6 and 31-33; and the addition of new Claims 48 and 49.

Any objection or rejection set forth in the previous Office action mail dated Mar 3, 2010 and not repeated herein is withdrawn.

Election/Restrictions

This application contains claims 7-9 and 27 drawn to an invention nonelected with traverse in the reply filed on December 13, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-4, 26 and 42-49 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 26 and 42-47, as amended remain, rejected; and newly submitted Claims 48 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not

Art Unit: 1655

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection remains for the reason set forth in the previous Office action but slightly altered with respect to Applicant's amendment to the claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2D 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Nature of the Invention. The claims are drawn to a method of modifying perception of body weight comprising administering to a first person for inhalation an effective amount of a composition that is hedonically positive to the male person and comprises a mixture of a floral odorant and a spice odorant in effective amounts such that an estimate by the male person of the body weight of a female person having a body mass index (BMI) of about 25 or greater is about 5-10% less than actual body weight of said female person and less than an estimate of the body weight of said second person by the male person before inhalation of the composition, wherein the floral odorant is selected from the group consisting of jasmine, lilac, lily of the valley, magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom and

Art Unit: 1655

carnation and mixtures thereof, and the spice odorant is selected from the group consisting of cinnamon, ginger, cloves, nutmeg oriental spice and mixtures thereof.

Breadth of the Claims. The claims are broad in that they are directed to a method of modifying perception of body weight comprising administering to a male person for inhalation an effective amount of a composition that is a mixture of claim-designated floral odorants and claim-designated spice odorants such that an estimate by the male person of the body weight of a female person having a body mass index (BMI) of about 25 or greater than an estimate of the body weight of the female person by the male person before inhalation of the composition, wherein the floral odorant is selected from the group consisting of jasmine, lilac, lily of the valley, magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom and carnation, and the spice odorant is selected from the group consisting of cinnamon, ginger, cloves, nutmeg and oriental spice (regardless of the age, sexual proclivity or sexual preference or ethnic background of the male person). The complex nature of the subject matter of the invention is clearly exacerbated by the breadth of the claims, particularly in view of the broadly different types and number of different types of floral odorants and spice odorants (natural or synthetic) used in the making of the claim-designated odorant mixture which requires effective amounts of each of the claim-designated odorants to effect the beneficial functional effect for modulation of perception of body weight of a female having a BMI greater than 25 when administered in effective amounts to a male who perceives the odorant mixture to be hedonically positive.

In response to the "Breadth of the Claims", Applicant argues that it is not required that the claimed inventions be limited to only males having particular characteristics. Applicant further argues, "Regardless of the male subject, it is implicit in the claims that the conditions of the method are not met unless administering the odorant composition as defined in the claims to the male subject achieves the recited effect. [New paragraph] One skill in the art would clearly recognize and appreciated whether or not the conditions of the claimed methods were met by assessing the effect of inhaling the composition to lessen the male's estimate of a female's weight after inhaling the odorant composition compared to before (without) inhaling the composition --- regardless of the male subject". Further arguments are directed to the idea that the odorants are specifically defined floral and spice odorants, which are well known in the art; and that they must be judged to be hedonically positive by the male individual and that the inhalation of the odorants will alter the male's perception of the female's body weight.

Applicant's arguments have been fully considered. However, they are not persuasive as the data set forth in the present specification indicate no significant results.

Guidance of the Specification and Existence of Working Examples. To determine the efficacy of a mixture of a floral odorant and a spice odorant to induce a change in men's perception of body weight of a female individual, Applicant conducted a study wherein a 5'9", 245 lb., white, cosmetic saleswoman with a body mass index (BMI) of 36.2 was used as a test model (first person). One hundred ninety-nine (199) male volunteers were used as observers (second person). The specification discloses

Art Unit: 1655

that the adult male volunteers surveyed were aged 12 to 61. Ninety-three percent (n=186) were white, 2 percent (n=4) were African-American descent, 3 percent (n=6) were Hispanic descent, and 1.5 percent (n=3) were Asian descent. The three odorants used in the test study (*i.e.*, Odorant #1 was a citrus and floral odorant mixture; Odorant #2 was a mixture of sweet pea and lily of the valley odorants; and, Odorant #3 was a mixture of floral and spice odorants) were judged to be hedonically positive by a panel at the Smell & Taste Treatment and Research Foundation, Chicago, Illinois. The specification further discloses application of the three odorants over a period of three consecutive days to the model at non-irritant, suprathreshold levels and in an amount that was predetermined to be adequate for normosmics to be able to detect the applied odorant at a non-irritant, suprathreshold level. The male volunteers gave estimations of the model's body weight with and without application of the three odorants; and, then the males were queried on their detection and hedonics of each of the Odorants 1-3. Applicant discloses statistically analyzing the gathered data for significance ($p < 0.05$).

In a test pilot study conducted prior to the test study, Applicant discloses applying a lavender odorant, a pumpkin pie odorant, and cinnamon odorant individually in three different sessions to a woman subject who had a BMI of 23.0 as opposed to a BMI of 36.2 of the model in the test study. Applicant disclose, "Despite the hedonically positive nature of the three odorants (*i.e.*, lavender, pumpkin pie, cinnamon), none of the three odorants provided a weight-reducing effect on the perception of a group of male observers. The men judged the model not to weigh any less in the presence of the three odorants that were tested."

In the results, the specification emphasizes that the pilot study and the test study only involved men's estimation of weight rather than women's on the basis that weight is a correlate of attractiveness in women, not men: "Weight inversely correlates with the level of attractiveness more often when men look at women than when women look at men. Also, 'societies' value women's physical attractiveness more because physical attractiveness represents a more salient way of evaluating women's [social] role fulfillment than it does for men [citation omitted]". From the results of the pilot study, Applicant concludes that the effect of the odorant/odorant mixture can be less pronounced in instances where an individual has a low body weight and is already perceived as being at a maximal attractive or ideal weight as opposed to an individual having a BMI of 36.2 (such as the model used in the test study). While Applicant theorizes that the instantly claimed invention is more effective in altering perception of an individuals whose BMI is greater than 25.0 (the medically defined threshold for being overweight), nowhere in the specification as originally filed does Applicant provide either a showing or data therefrom to substantiate the alleged theory. The Office notes that the pilot study did not involve either a female or a male model having a BMI greater than 25. The Office further notes that the specification fails to disclose whether any of the three pilot test odorants had a weight-increasing effect on the perception of the group of male observers or what was the tolerance window rate for either correctly or incorrectly estimating the weight of the model in the absence or presence of the tested odorant(s) used by Applicant to determine that the men did not judge the female model 'not to weigh any less in the presence of the three odorants that were tested'.

Of most interest, the specification discloses, “The test study demonstrated that of the three odorant mixtures tested, only the use of a floral-spice odorant mixture had a specific effect and provided a perceived reduction of weight. In the test study, among the 50 males tested with the woman model wearing the odorant mixture of floral and spice odorants (Odorant #3), there was noted a significantly reduced perception of weight ($p=0.02$) compared to the control trials. This was a reduction of perceived weight by 4.01 pounds (a 2.4% reduction) as compared to the “no odor” control group in which the averaged perceived weight by 49 males was 172.8 pounds. Among the 100 males tested, neither the citrus-floral odorant mixture (Odorant #1) nor the sweet pea and lily of the valley odorant mixture (Odorant #2) were effective in reducing perception of weight ($p=0.1, 0.01$).

In those males who perceived Odorant #3 to be hedonically positive ($n=16$), the effect of the odorant on perceived weight of the model was even more substantial at 160.8 pounds (averaged), which was 12 pounds less than the actual weight measurement ($p=0.02$). The inhalation by those test subjects of the floral-spice odorant mixture applied to the model resulted in a 7% reduction in perceived weight ($p=0.02$) compared to the no odor control subjects.”

Applicant argues that sufficient supporting disclosure, both through the working example and descriptive discussion, teach those of ordinary skill in the art how to make and use the invention as broadly as it is claimed, and show that the odorant mixtures are useful in providing the recited effect. Applicant further argues that the present disclosure includes a working example that is more than adequate to enable one of

Art Unit: 1655

ordinary skill in this art area to carry out the invention commensurate with the scope of claims. This is not persuasive because Applicant has not demonstrated or specifically disclosed which floral odorant or floral odorants and which spice odorant or spice odorants can be used to provide the making of a composition comprising a hedonically positive mixture of a floral odorant(s) and a spice odorant(s) such when combined in effective amounts and administered in effective amounts to a first person for inhalation that the first person would perceive the body weight of the second person to be about 5-10% less than the actual body weight of the second person. For instance, while the specification discloses examples of floral odorants (such as those recited in the Markush group of currently amended Claim 1) and spice odorants (such as those recited in the Markush group of currently amended Claim 1), nowhere in the specification does Applicant disclose, even by the example of the disclosed Odorant #3, which odorants could be used to produce a composition comprising a hedonically mixture of a floral odorant and a spice odorant in effective amounts to cause the claim-designated functional weight for modifying perception of body weight or what criteria or variables to consider to arrive at such a composition. The specification merely describes a hedonically positive odorant or odorant mixture as one to which an individual has a pleasant or positive reaction to its scent. In fact, the specification fails to provide any example of "a hedonically positive mixture of a floral odorant and a spice odorant" detailing the actual ingredients contained therein to provide the functional effect for modifying perception of body weight. Moreover, the Office notes that nowhere in the specification does Applicant describe how the Smell & Taste Treatment and

Art Unit: 1655

Research Foundation determined the positive hedonics of Odorant #3 or what was the gender, age, sexual proclivity or sexual preference or ethnic background of the panel determining the hedonics of the odorants or odorant mixtures used in either the pilot test or test study or whether any of the odorants or odorant mixtures provided a modifying perception of body weight in the panel members. Furthermore, it is noted that the odorants are not limited to naturally occurring odorants or synthetic versions of natural occurring versions of the claim-designated floral and spice odorants. Given the variety of the claim-designated floral odorants and the claim-designated spice odorants, the skilled artisan could not reasonably extrapolate those odorants which could be mixed or the amounts of the individual floral odorants and individual spice odorants which could be mixed to produce a composition comprising a hedonically positive mixture such when administered in effective amounts would cause a modification of body weight due to the limited guidance of the specification.

Applicant urges that the results of the test study demonstrate that only administration of floral-spice odorant mixture had a specific effect and provided a perceived reduction o body weight. However, the Office notes that the data presented in the specification as originally filed contradicts Applicant's assertion that the instantly claimed method indeed works. For example, the statistical analysis of the data presented in the instant disclosure warrants question because of the following:

"In the test study, among the 50 males tested with the woman model wearing the odorant mixture of floral and spice odorants (Odorant #3), there was noted a significantly reduced perception of weight ($p=0.02$) compared to the control trials. This was a reduction of perceived weight by 4.01 pounds (a 2.4% reduction) as compared to the "no odor" control group in which the averaged perceived weight by 49 males was 172.8 pounds. [text omitted] In those males who perceived Odorant #3 to be hedonically

Art Unit: 1655

positive (n=16), the effect of the odorant on perceived with of the model was even more substantial at 160.8 pounds (averaged), which was 12 pounds less than the actual weight measurement (p=0.02). The inhalation by those test subjects of the floral-spice odorant mixture applied to the model resulted in a 7% reduction in perceived weight (p=0.02) compared to the no odor control subjects.”

The Office notes that the woman model used in the test study of the three odorant/odorant mixtures weighed 245 lbs. Nonetheless, among the 50 males tested with the woman model wearing Odorant #3, the males tested perceived her weight to be only 4.1 pounds less as compared to the “no odor” control group. The males tested with the woman wearing Odorant #3 perceived the model’s body weight to be 168.8 pounds, whereas the averaged perceived weight of the “no odor” male control group perceived the model’s weight to be 172.8 pounds, whereas those males who perceived Odorant #3 to be hedonically positive (n=16) perceived weight of the model was 160.8 pounds. Given that no data was provided by Applicant to demonstrate what was the tested males’ perception of the body weight of the woman model wearing either Odorant #1 or Odorant #2, it is unclear as to whether there was indeed a significant difference achieved among the three tested odorants because the data presented in the specification fails to explain why the tested Odorant #3 group estimated the weight of a woman weighing 245 pounds as being only 4.1 pounds less than the “no odor” control group or why the tested Odorant #3 group who perceived the odorant to be hedonically positive estimated the woman weighing 245 pounds as being only 12 pounds less than the “no odor” control group, especially given that the specification fails to disclose what number of men in the “no odor” control group considered the odorant to be hedonically positive and what was the difference in estimated perceived body weight of the female

between the two groups (no odor vs. tested odor), wherein both groups of men perceived the odorant to be positively hedonic.

Moreover, it is unclear from Applicant's disclosure whether the pilot study included the same male volunteers used in the test study. The Office notes that Applicant emphasizes that the males in the pilot study did not underestimate the body weight of the woman model having a BMI of less than 25, whereas the males in the test pilot study radically underestimated the weight of the model having a BMI of 36.2. In other words, it is unclear from Applicant's disclosure what was the ability of the men tested with the three odorant/odorant mixtures to properly estimate the weight of an overweight woman or whether other factors other than the influence of the floral-spice odorant mixture played a role in the men's gross underestimation of the apparently obese woman, given that the men had observed the same female model having the same approximate weight over a three consecutive day period of olfactory testing and were questioned as to how much the woman model weighed. Furthermore, given that Applicant's data provides evidence that the estimated weight of the control group was 30% less than the actual body weight of the female model weighing 245 lbs and having a BMI of 36.2; and, given that the rate of error of the "no odor" control group exceeds more than three times the measured difference between the control (placebo) and experimental "tested odor" group, Applicant's reported data appears to be inconclusive at best instead of being statistically significant or providing the claim-designated rate of modified body weight reduction; and, therefore, fails to support patentability for the claimed subject matter.

With regard to the “Guidance of the Specification and Existence of Working Examples”, Applicant argues, “At page 11 of the Office Action, the Examiner argues that there is no support for the limitation of the female person having a BMI of greater than 25.” This is not true. Applicant is invited to revisit the previous Office action wherein it is clear that the Examiner is referring to the BMI of the female used in the pilot study.

Applicant’s argument that it is irrelevant that the specification fails to address whether or not the pilot test odorants produced a weight-increasing effect would be well taken if not for the fact that Applicant’s idea for the ‘workability’ of the claimed invention is predicated on the following, as set forth on page 16, lines 13-25 of the instant specification:

“The results of the pilot study indicate that the effect of the odorant/odorant mixture can be less pronounced in cases in which the individual has a low body weight and is at a maximally attractive weight, such that the observer may or may not perceive the individual as weighing less, and/or relates a low body weight as being too thin and unattractive. Although Applicant does not intend to be bound by theory, it is believed that there is a body mass threshold at which the odorant/odorant mixture does not significantly alter the perception of body weight due to the body size of the individual. In the pilot study, the model was not judged to weigh any less in the presence of any of the three odorants. The model’s BMI was 23.0 as opposed to the BMI of 36.2 of the model in the test study. It is believed that the model in the pilot study was already at a maximal attractive weight, and that the method of the invention is more effective to alter perception of the body weight of individuals whose BMI is greater than 25.0, the medically defined threshold for being overweight. (National Heart, Lung, and Blood Institute, Body Mass Index Table: Obesity Guidelines (2001))”.

Further arguments are directed to the idea that Applicant has adequately described how to determine the hedonic nature of an odorant or odorant mixture and how to screen and assess an odorant or odorant mixture for positive or negative hedonics within the knowledge of the art; and, therefore, one skilled in the art would

Art Unit: 1655

clearly be able to identify a hedonically positive odorant mixture for use in the methods as claimed.

Applicant's arguments have been fully considered. However, they are not persuasive because the data presented in the specification indicate no significant results for the claimed process; and, therefore one of skill in the art would not be able to make and/or use the method as instantly claimed.

Predictability and State of the Art. Applicant's premise for inducing a perception of weight reduction in a male observer of an obese woman is predicated on the idea that society, as a whole, perceives a thinner body image as being more attractive than overweight subjects, specifically females. This premise is specifically directed to the idea that men deem thinner women to be more attractive than obese women and that women generally perceive their social attractiveness or self-image in terms of how others perceive her weight. Given the foregoing, Applicant further urges that women understanding that those believing that she is overweight will try to attempt to project the visual image of thinness. While Applicant's premise may apply to some sectors of the population, this is not true in all societies or ethnic backgrounds. For example, Miller et al. (U; Miller, K. J. et al. International Journal of Eating Disorders (4/2000); 27(3): 310-6. Comparisons of body image dimensions by race/ethnics and gender in a university population.) teaches, "Some research suggests that, among African-Americans, the ideal body size is larger than amount European Americans and that size is less salient in judging attractiveness." (See page 311, second paragraph). Miller further teaches that while less research has been conducted among the Hispanic

Art Unit: 1655

population, Guatemalan college women felt better about their bodies and were less concerned about their weight than their counterpart European American white college females, despite the fact that appearance was equally important to both groups. (See page 311, third paragraph). In a study comparing the affective and cognitive components of body image related to physical appearance, weight and health among three racial/ethnic groups, Miller reports that a pattern of racial/ethnic and gender differences exist between men and women of African American, European American and Latino/a American racial/ethnic groups. Applicant's disclosure fails to consider these differences among men and women of different racial/ethnic backgrounds and how these differences would affect the claim-designated method for modifying perception of body weight in those men and women having a positive self-image of body weight considered by European Americans as less than attractive. Most important nowhere in the specification does Applicant indicate whether the males tested were queried as to what was the ideal weight of attractive women. Even more important, nowhere in the specification did Applicant disclose what was the self-body image of the woman weighing 245 pounds before the testing or whether the odorant/odorant mixtures affected a sense of well-being or a perceived weight-reducing effect in the woman such that she had a better feeling about herself. Despite Applicant's apparent omission that the claimed method would not be operable is modifying a woman's perception of body weight in other subjects, the claims broadly read on a method of modifying weight perception in all sectors of the population. See

<http://pherolibrary.com/forum/showthread.php?t=6442>. (V).

Furthermore, the state of the prior art at the time the specification was filed was such that few studies dealt with the accuracy of visual weight estimations anywhere (See page 220, Column 2, first paragraph of Hall et al. (W; The Journal of Emergency Medicine (2004): 27(3): 219-224. Errors in weight estimation in the emergency department: Comparing performance by providers and patients)). Moreover, Hall taught that visual weight estimations of even health care providers are grossly inaccurate and that gender did not create a bias in provider accuracy, although providers were more likely to underestimate women's weight than men's. Hall also showed that providers were more than twice as likely to underestimate patient's weight than to overestimate it. In another instance, when Hendershot et al. (X; Hendershot, K. M. et al. Journal of the American College of Surgeons (12/2006); 203(6): 887-893. Estimated height, weight, and body mass index: Implications for research and patient safety.) had health care providers to visually estimate the weight of patients, health care providers tended to underestimate weight especially as the actual BMI number increased. Finally, Crandall et al. (U1; Crandall C. S. et al. Air Medical Journal (May-June 2009) ;28(3):139-45. Estimation of total body weight in obese patients.), like Hall and Hendershot, taught, "Visual estimation of weight has been shown to be a poor predictor of total weight, particularly in obese patients." See page 143, first Column to second Column, first paragraph.

In response to "Predictability and State of the Art", Applicant notes that the subject matter of the references of Hall 2004, Hendershot 2006 and Crandall 2009 is

Art Unit: 1655

evidence of the lack of accuracy of visual estimates of body weight. Thereby, Applicant argues that the claims have been amended to clarify that administering the defined odorant composition is to modify perception of female's weight based on a reduced estimate of weight after inhaling the composition compared to an estimate of weight before (without) inhaling the composition. Thus, Applicant concludes that the accuracy of estimating a female's actual is not required by the claims.

It appears that Applicant asserts that the above-mentioned cited references are not relevant to Applicant's claimed invention. However, this is not persuasive because an estimate of the weight of an observer of another's weight is no more than the observer's 'perception' of the weight of the second person or perceived weight of the second person. Given that the cited references provide evidence that various factors such as psychological conditioning, gender bias, *etc.* play a role to effect modification of perceived body weight in men of the weight of individuals particularly females having a BMI greater than 25, the references are considered significant to the limitations of the claimed invention, absent evidence to the contrary.

Amount of Experimentation Necessary. The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the limited guidance of the specification, the prior art to teach how to make and/or use the instantly claimed method for modifying perception of body weight comprising administration of an effective amount of a hedonically positive mixture of the claim-designated floral odorant(s) and the claim-designated spice odorant(s). In order to

Art Unit: 1655

practice the claimed invention, one of skill in the art would have to first envision a combination of an effective amount of a floral odorant to be combined with an effective amount of a spice odorant to provide for the making of an odorant mixture which is hedonically positive to a male person for inhalation, an effective dosage amount of the odorant mixture to be administered, duration of treatment, route of administration of treatment (*e.g.*, application to the male person (observer) and/or application to the female person, *etc.*), and an appropriate experimental model system to determine whether or not the combination is effective for modifying perception of body weight such that an estimate by the male person of the body weight of a female person having a body mass index (BMI) of about 25 or greater is less than an estimate of the body weight of the female person before inhalation of the composition, wherein the floral odorant is selected from the group consisting of jasmine, lilac, lily of the valley, magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom, carnation and mixtures thereof, and the spice odorant is selected from the group consisting of cinnamon, ginger, cloves, nutmeg, oriental spice and mixtures thereof. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding use of odorants to modify perception of body weight or prior art regarding using visual observation as a reliable tool for humans to correctly estimate the weight of those having a BMI greater than 25 even in the absence of an odorant, one of skill in the art would have to then either envision a modification of the first combination of odorants, odorant dosage, duration of treatment, route of administration, *etc.*, and appropriate model system for testing the odorant mixture, or envision an entirely new

Art Unit: 1655

combination of the above and test the system again. In order to practice Applicant's invention, it would be necessary for one to conduct the preceding experimentation for each of the claim-designated combinations of a floral and a spice odorant (or combinations thereof a mixture of floral odorants and a mixture of spice odorants) because there is no known mixture of the claim-designated odorants for affecting modification of body weight perception, as instantly claimed by Applicant, or allegedly exemplified by Applicant in the 'working example'. Thus, in view of the breadth of the claims and the lack of guidance provided by the specification and limited number of working examples, as well as the unpredictability of the art, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to make and/or use the instantly claimed method. *Genetech*, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, a method of modifying perception of body weight, comprising:
administering to a male person for inhalation an effective amount of a composition that is hedonically positive to the male person and comprises a mixture of a floral odorant and a spice odorant in effective amounts such that an estimate by the male person of the body weight of a female person having a body mass index (BMI) of about 25 or greater is less than before inhalation of the composition, wherein the floral odorant is selected from the group consisting of jasmine, lilac, lily of the valley,

Art Unit: 1655

magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom, carnation and mixtures thereof, and the spice odorant is selected from the group consisting of cinnamon, ginger, cloves, nutmeg, oriental spice and mixtures thereof is not considered to be enabled by the instant specification.

In response to “Amount of Experimentation Necessary”, Applicant argues that the Examiner argues that there is no requirement for a working example under the enablement requirement of Section 112(1); and, that instead the proper inquiry under *In re Wands* is the amount of experimentation that is necessary in order for one skilled in the art to practice the invention as claimed. Applicant’s arguments are not persuasive. The Examiner must evaluate the data presented in the disclosure as it pertains to the claimed subject matter. Herein, Examiner’s initial analysis finds that the data presented in the disclosure provides no significant results for practicing the invention as claimed.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Further arguments are directed to the idea that the specifications provides sufficient supporting disclosure, both through the descriptive disclosure and

Art Unit: 1655

experimental example showing guidance and what is well known to those of ordinary skill in the art, to teach one of skill in the art how to make and use the invention as broadly as it is claimed. While fully considered, Applicant's arguments are not persuasive because the Examiner's complete analysis of the claimed invention with regard to all of the relevant *Wands* factors fully supports a conclusion of lack of enablement for the invention, as broadly claimed. Thereby, Applicant's arguments are rendered moot.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1655

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE FLOOD whose telephone number is (571)272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 14, 2010

/Michele Flood/
Primary Examiner, Art Unit 1655

Application/Control Number: 10/690,791
Art Unit: 1655

Page 23